REMARKS

Claims 1-12, 14, 16, 21, and 25-30 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-21 of U.S. Patent No. 7,408,156. Reconsideration is requested.

Independent claim 1 of the present application is directed to a method of producing images of infrared (IR) radiation of a patient. The method includes providing an IR imaging camera configured to receive IR radiation from an array of optical elements (optels) in a field-of-view viewable by the IR imaging camera. Plural frames of IR radiation are acquired from a patient positioned in the field-of-view, with each frame acquired during a corresponding frame sample interval and with each frame corresponding to the IR radiation acquired from the array of optels during its frame sample interval. Plural rates-of-change of IR radiation received from the array are determined, with each rate-of-change determined for the IR radiation received from the same optel in at least two frames. Each rate-of-change is mapped to a color or shade of gray. The color or shade of gray assigned to each integral is mapped to a position in an image corresponding to the position of the corresponding optel in the field in view.

As can be seen, independent claim 1 requires determining plural rates-of-change of IR radiation received from the array, with each rate-of-change determined for the IR radiation received from the same optel in at least two frames. In contrast, the claims of U.S. Patent No. 7,408,156 required determining plural integrals of IR radiation received from an array, with each integral determined for the IR radiation received from the same optel in at least two frames.

It is well known in the mathematical art of calculus that a rate-of-change (e.g., derivative) equates to a slope of a line of a function and that an integral equates to an area under a curve of a function. The slope of a line of a function and the area under a curve of the function are two completely different mathematical concepts that have different purposes in the art, i.e., a slope of a line versus an area under a curve. In the present invention, each rate-of-change (e.g., derivative) determined from IR radiation received from the same optel in two or more frames conveys different information about the underlying physiological process than would an integral of said IR radiation. Hence, an image produced based on rates-of-change (e.g., derivatives) of IR radiation will display different physiological information than an image produced based on

integrals of said IR radiation (because of the different values obtained), and said images will, therefore, convey different diagnostic information.

When considered in light of the different diagnostic information conveyed by an image produced in accordance with the present invention (i.e., rates-of-change or derivatives) versus an image produced based on integrals of IR radiation, the scope of the claims of the present invention is indeed completely different than the scope of the claims of the '156 patent. To this end, in the absence of some teaching suggestion, or motivation, one skilled in the art would not consider substituting rates-of-change (in the present application) for integrals (in the '156 patent), or vise versa, since there is no guarantee that such substitution would yield any diagnostically useful information regarding the underlying physiological process. Rather, one skilled in the art would understand that the purpose for determining a rate-of-change (derivative) (e.g., to determine a slope of a line) is completely different than the purpose for determining an integral (e.g., to determine an area under a curve) and would simply have no reason or motivation to substitute one for the other. The fact that derivatives and integrals are used for different purposes is readily apparent from any recognized textbook on calculus which clearly shows that differentiation and integration are different topics meriting separate treatment (see, e.g., the attached copy of the table of contents from the textbook "Calculus: One and Several Variables with Analytic Geometry, Third Edition", by S. L. Salas, copyright 1971, 1974, and 1978 by John Wiley & Sons, Inc., wherein differentiation (Chapter 3) and integration (Chapter 5) are treated as different topics).

Moreover, the mere fact that the techniques of differentiation and integration are mentioned in the same textbook on calculus is not dispositive that these techniques can be substituted for each other when analyzing physiological processes absent some disclosure, teaching, or suggestion that such substitution would produce a useful or meaningful diagnostic result. To the contrary, absent any such disclosure, teaching, or suggestion, the use of integrals in the '156 patent teaches away from the use of rates-of-change in the present application.

In the Office Action, the Examiner admits that the claims of the present application and the claims of U.S. Patent No. 7,408,156 are not identical. However, the Examiner goes on to allege that "the claims of the '156 patent disclose substantially the same

scope of invention of the instant application when the fundamental theorem of calculus is taken into account". This allegation is simply incorrect. The mathematical techniques disclosed in the present application and in the '156 patent are used for exploring and identifying physiologic processes in mammals. Each technique operates on the data to achieve a different diagnostic result. The mere disclosure of one mathematical technique in the '156 patent (namely, integration) does not guarantee, teach, or suggest that the use of a different mathematical technique (namely, rate-of-change or derivative) in the present application will produce any useful or meaningful data or results. To this end, absent some disclosure, teaching, or suggestion that rates-of-change or derivatives can be substituted for integration, one skilled in the art would have no reason to believe that such substitution would produce meaningful results and, therefore, would simply not consider such substitution.

Accordingly, the use of rates-of-change in the present application cannot be considered obvious in view of the use of integrals in the '156 patent and withdrawal of the nonstatutory obviousness-type double patenting rejection in the Office Action is requested.

Claims 1-12, 14, 16, 21, and 25-30 are pending in the application and stand rejected under 35 U.S.C. § 103(a) for obviousness from the various teachings of U.S. Patent documents 4,428,382 to Walsall et al.; 6,023,637 to Liu et al.; 6,081,577 to Webber; 6,216,540 to Nelson et al.; 5,533,139 to Parker et al.; and 5,692,510 to Gordon et al. Reconsideration is requested.

Independent claim 1 recites a method of producing images of IR radiation of a patient that includes, among other things, determining plural rates-of-change (e.g., derivatives) as a function of the IR radiation acquired from an array, with each rate-of-change (e.g., derivative) corresponding to a change of the IR radiation received from the same optel of the array in at least two frames. Each rate-of-change (e.g., derivative) is mapped to a color or shade of gray which in turn is positioned in an image corresponding to the position of the corresponding optel in the field-of-view. Independent claim 14 recites an infrared imaging apparatus that includes a workstation for determining plural rates-of-change (e.g., derivatives) as a function of IR radiation received from an array of optels by a means for detecting, with each rate-of-change (e.g., derivative) corresponding to the change of IR radiation acquired from the same optel in at

least two frames. The workstation maps each rate-of-change (e.g., derivative) to a color or shade of gray and maps the color or shade of gray of each rate-of-change (e.g., derivative) to a position in an image corresponding to the position of the corresponding optical element in the field-of-view. Lastly, independent claim 25 recites an infrared imaging apparatus that includes a means for determining plural rates-of-change (e.g., derivatives) as a function of IR radiation received by a means for detecting from an array of optels, with each rate-of-change (e.g., derivative) corresponding to a change of IR radiation acquired from the same optel in at least two frames. The means for determining maps each rate-of-change (e.g., derivative) to a color or shade of gray which in turn is mapped to a position in an image corresponding to the position of the corresponding optel in the field-of-view.

Claims 1, 14, and 25:

In the detailed rejection of claims 1-7, 10, 12, 14, 16, 21, 25-27, and 29, the Examiner alleges as follows:

> Walsall et al discloses a method and apparatus for IR imaging data frame acquisition over an interval so as to map IR radiation data acquired by the imager over multiple frames to detect abnormalities in the tissue being interrogated. Normalization of temperature ranges (Col 9 Line 5-Col 11 Line 65), acquisition occurs over multiple time intervals with data acquisition occurring during both a static and stressed state (Col 5 Line 40-Col 6 Line 35, Col 6 Line 40-Col 7 Line 35). Data is manipulated to show the change in temperature over a time period (Col 9 Lien 5-Col 10 Line 35) and data points are used and plotted to show variations in temperature which indicate pathological abnormalities.

Assuming *arguendo* the foregoing allegation is accurate, it does not address the limitations of the claims which generally require determining plural rates-of-change of IR radiation received from an array of optels, with each rate-of-change corresponding to a change of IR radiation required from the same optel in at least two frames. Accordingly, the foregoing language from the Office Action cannot establish a *prima facie* case of obviousness for the limitations of the claims, either alone or in combination with the Liu et al. patent also relied upon in the rejection of the claims.

Notwithstanding the foregoing, the Walsall et al. patent does not teach or suggest determining plural rates-of-change and mapping each rate-of-change to a color or shade of gray

which is then mapped to a position in an image corresponding to the position of the corresponding optel in the field-of-view, as is expressly required of the claims. Rather, the Walsall et al. patent discloses using average temperatures for determining abnormal tissue, not rates-of-change (see e.g., Walsall et al. col. 8, lines 28-30, and 56-63; col. 10, lines 32-65, especially line 55 "Average Breast Temperature ('BA')"; col. 11, lines 11-15, 37-39, 47, 52-54, and 68). The average temperatures in the Walsall et al. patent are utilized to determine an index score. The index score "ranging from 1 to 99, ranks the patient relative to thousands of other patients whose breast temperature data serves as a data base, and provides a measure of the patient's relative risk with respect to breast cancer" (see Walsall et al. col. 9, lines 21-33).

The present invention does not require the use of normalization (see Walsall et al., column 12, lines 8-12), the calculation of average temperatures (see references to Walsall et al. above regarding average temperatures), or any comparison to arbitrary or empirical "standards" for determination of abnormalities (see Walsall et al. col. 9, lines 21-33). Rather, the present invention determines abnormal physiological processes in an individual, particularly angiogenesis associated with tumor growth and development, directly from the individual without regard to comparing the individual with any other individual. The disclosure in the Walsall et al. patent of the use of normalization, calculation of average temperatures, and the use of arbitrary or empirical standards for determination of abnormalities simply cannot disclose, teach, or suggest the present invention, especially the use of rates-of-change.

The Liu et al. patent does not cure the foregoing deficiencies in the teachings of the Walsall et al. patent. Specifically, col. 15, line 19 through col. 16, line 41, and Figs. 17 and 18 of the Liu et al. patent disclose defining an output intensity window 162 comprising a range of intensity values preferably smaller than a range of intensity values in an input intensity window 155. Each increment in the output intensity window 162 is mapped to a color value in a color spectrum 156. An output intensity scaling factor, e.g., ½, is utilized to define a range of the output intensity window 162 with respect to the range of the input intensity window 155. For example, if the input intensity window 155 has a range of 25.60 intensity increments, the output intensity window 162 is selected to have ½ of that range or 12.80 intensity increments. Having

selected the output intensity scaling factor, the output intensity window 162 is mapped to spectrum 156 as shown in Fig. 17.

With reference to Fig. 18, and with continuing reference to Fig. 17, since output intensity window 162 is smaller than input intensity window 155, it is possible for output intensity window 162 to fall in any 12.80 increment range of the 25.60 increment range of the input intensity window 155. Thus, it is possible to "slide" or adjust the output intensity window 162 up and down within the range of input intensity window 155. For example, as shown in Fig. 18, output intensity window can be adjusted from a first position 162′ in which it is mapped to an intensity range between 26.70 and 39.50; to a second position 162″ in which it is mapped to an intermediate intensity range between 22.00 and 35.00; and to a third position 162‴ in which it is mapped to an intensity range between 13.90 and 26.60. In each case, while the intensity range to which the output window 162 is mapped is adjusted, the output window 162 continues to be mapped to the entire color spectrum 156.

Adjustment of the position of output intensity window 162, as shown in Fig. 18, is referred to as a "slicing" function due to a visual effect that is produced as a result of the adjustment. The "slicing" image can be displayed by mapping each input data value to a color in the output window 162. Importantly, the Liu et al. patent discloses that the "slicing" function is performed on a single input image, not a plurality of images.

In contrast, the independent claims of the present application generally recite that plural frames of IR radiation are acquired from a patient position in the field-of-view of an IR imaging camera with each frame acquired during a corresponding frame sample interval and each frame corresponding to the IR radiation received by an array of optels during the frame's sample interval. Plural rates-of-change (e.g., derivatives) of IR radiation received by the array are determined, with each rate-of-change (e.g., derivative) determined for the IR radiation received by the same optel in at least two frames. Each rate-of-change (e.g., derivative) is mapped to a color or a shade of gray and the color or shade of gray of each rate-of-change (e.g., derivative) is mapped to a position in an image corresponding to the position of the corresponding optel in the array.

The Liu et al. patent neither discloses acquiring plural frames of IR radiation nor discloses determining plural rates-of-change of IR radiation received by the array, with each rate-of-change determined for the IR radiation received by the same optel in at least two frames.

As can be seen, the Walsall et al. and Liu et al. patents, either individually or in combination, do not disclose, teach, or suggest determining plural rates-of-change as a function of IR radiation acquired from an array of optels, with each rate-of-change corresponding to a change of the IR radiation received from the same optel in at least two frames, and mapping each rate-of-change to a color or a shade of gray and mapping the color or shade of gray of each rate-of-change to a position in an image corresponding to the position of the corresponding optel in the field-of-view.

Absent disclosing, teaching, or suggesting a method having all the limitations of claim 1 or apparatuses having all the limitations of claims 14 and 25, the Walsall et al. and Liu et al. patents, either individually or in combination, cannot render obvious these claims, or claims 2-12, 16, 21, or 26-30 dependent therefrom.

Claim 4:

Claim 4 recites that determining each rate-of-change in claim 1 includes determining a first derivative or a second derivative. As discussed above, the Walsall et al. and Liu et al. patents, either individually or in combination, do not disclose determining rates-of-change of IR radiation in any manner. Accordingly, the Walsall et al. and Liu et al. patents, either individually or in combination, cannot disclose, teach, or suggest determining each rate-of-change by way of a first derivative or a second derivative.

Absent disclosing, teaching, or suggesting a method having all the limitations of claim 4, the Walsall et al. and Liu et al. patents, either individually or in combination, cannot render obvious claim 4.

Claim 28:

Claim 28 recites that the means for controlling controls the means for detecting to acquire the plurality of frames logarithmically over an imaging interval, wherein the acquisition occurrence increases late in the imaging interval. The detailed rejection of claim 28 in the Office Action relies upon the Parker et al. patent for disclosing real-time logarithmic image acquisition

(col. 3, lines 5-8). However, the logarithmic image acquisition referred to in the Parker et al. patent is logarithmic processing of acquired data – not the logarithmic acquisition of plural frames over an imaging interval, wherein the acquisition occurrence increases late in the imaging interval.

Absent disclosing, teaching, or suggesting an apparatus having all the limitations of claim 28, the Walsall et al., Liu et al, and Parker et al. patents, either individually or in combination, cannot anticipate or render obvious claim 28.

CONCLUSION

Based on the foregoing remarks, reconsideration of the rejections and allowance of claims 1-12, 14, 16, 21, and 25-30 are requested.

Respectfully submitted,

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